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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/464,528	12/15/1999	SAVERIO CARL FALCO	BB1205-US-NA	7694

23906 7590 04/22/2003

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
1638	30

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/464,528	FALCO ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Cynthia Collins	1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 28 October 2002.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 13-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 13-24 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) Interview Summary (PTO-413) Paper No(s). 22
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

**DETAILED ACTION**

The Amendment filed October 28, 2002 paper no.24 has been entered.

Claims 1-11 are cancelled.

Claims 13-24 are newly added. Applicant should note that newly added claims 12-23 have been renumbered as claims 13-24 in accordance with Rule 1.126.

Claims 13-24 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

***Claim Rejections - 35 USC § 112***

Claims 13-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed May 22, 2002.

Claims 13-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid fragment having constitutive promoter activity comprising the nucleic acid sequence of SEQ ID NO:6 and an isolated nucleic acid fragment having constitutive promoter activity comprising the nucleic acid sequence of SEQ ID NO:14 in which the AG dinucleotide at positions 2161-2162 is changed to CC, does not reasonably provide enablement for an isolated nucleic acid fragment having constitutive promoter activity

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comprising any subfragment of SEQ ID NO:6, or an isolated nucleic acid fragment having constitutive promoter activity comprising any subfragment of SEQ ID NO:14. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record set forth for claims 1-11 in the office action mailed May 22, 2002.

Applicant's arguments filed October 28, 2002, have been fully considered but they are not persuasive.

Applicant argues that the claims as rewritten address the concerns raised with respect to 35 USC 112, first paragraph. Applicant points out that SEQ ID NO:6 is a subfragment of SEQ ID NO:14, and that SEQ ID NO:14 has been shown to have promoter activity (reply pages 8-9).

First, the claims as rewritten do not address the concerns raised with respect to 35 USC 112, first paragraph, for written description, because the specification does not describe a representative number of species to support a description of the genera "isolated nucleic acid fragments having constitutive promoter activity comprising any subfragment of SEQ ID NO:6" and "isolated nucleic acid fragments having constitutive promoter activity comprising any subfragment of SEQ ID NO:14". While the specification does describe one subfragment of SEQ ID NO:14 that has promoter function, namely SEQ ID NO:6, the Examiner maintains that the description of only one subfragment of SEQ ID NO:14 is not sufficient to describe the genus "isolated nucleic acid fragments having constitutive promoter activity comprising any subfragment of SEQ ID NO:14". Additionally, the specification does not describe any subfragment of SEQ ID NO:6 that has promoter function.

Second, the claims as rewritten do not address the concerns raised with respect to 35 USC 112, first paragraph, for scope of enablement, because the specification does not provide sufficient guidance for one skilled in the art to determine, without undue experimentation, which subfragments of SEQ ID NO: 6 would have constitutive promoter function and which would not, and which subfragments of SEQ ID NO:14 would have constitutive promoter function and which would not, because the specification does not provide guidance with respect to which nucleotides would need to be retained by a subfragment of SEQ ID NO: 6 or SEQ ID NO:14 such that the subfragment would retain constitutive promoter function.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13 and 21, and claims 14-20 and 22-24 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is indefinite in the recitation of "under stringent conditions". It is unclear what conditions would yield the claimed isolated nucleic acid fragments, as it is unclear what constitutes "stringent conditions". It is suggested that the claim be amended to recite specific hybridization conditions.

Claim 13 is indefinite in the recitation of "CARL AND ZHONSEN: IS THIS OK? CONDITIONS IN EXAMPLE 3 WERE STRINGENT." It is unclear what is intended by this phrase. The phrase also constitutes a second sentence as it follows a period in claim 13. As the

quoted phrase appears to be an unintentional mistake, it is suggested that the phrase be deleted from the claim.

Claim 13 is also indefinite for depending on claim 1, which has been cancelled.

Claim 21 is indefinite in the recitation of the phrases "increasing or decreasing the expression of at least one heterologous nucleic acid fragment" and "wherein the expression of the heterologous nucleic acid fragment is increased or decreased". The "at least one heterologous nucleic acid fragment" is operatively linked to a promoter. Because a promoter *promotes* the transcription of the nucleic acid sequence to which it is operatively linked, the phrases "increasing or decreasing the expression of at least one heterologous nucleic acid fragment" and "wherein the expression of the heterologous nucleic acid fragment is increased or decreased" are indefinite and confusing, since it is unclear how the expression of the heterologous nucleic acid fragment could both increase and decrease under the control of a promoter.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Remarks***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC  
April 18, 2003

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 1638

*David T. Fox*  
for Elizabeth F. McEwan,  
Ph.D